REMARKS

Claims 1-23, 38-45 and 51-58 are pending in the application. Claims 12, 41 and 43 stand withdrawn from consideration as being drawn to a non-elected species as a result of an earlier election requirement. Claims 24-37 and 46-50 have been cancelled as a result of an earlier restriction requirement. Pursuant to the October 5, 2004 Office Action, Claims 1-11, 13-23, 38-40, 42, 44, 45 and 51-58 stand rejected.

By the foregoing amendment:

- Independent Claims 1 and 38 have been amended to specify that the hydrophilic polymers must have a water content, at equilibrium, of at least 5% by weight. This change gives more specificity to the term "hydrophilic" and is supported by the specification at page 12, lines 12-13. Further, Applicants wish to point out that their use of the term "encapsulated" includes those particles that are fully as well as partially encapsulated, i.e., where a portion of the encapsulated or encased antimicrobial particle(s) is exposed at the surface of the microcapsules. Such a happenstance is inherent from the specification, particularly in light of that method of manufacture of the microcapsule wherein the hydrophilic polymer and antimicrobial agent are compounded and the so formed composition is ground to the desired particle size. (See page 17, lines 12-26)
- Claims 8 and 9 have been cancelled in light of the foregoing amendment to claim 1.
- Claims 10 and 11 have been amended to correct their dependency in light of the cancellation of Claim 8.
- Claims 51-54 have been amended to change their dependency and correct the error with respect to the particle size ranges claimed. In the latter respect, Applicants have established two lines of claims, those wherein individual particles of the antimicrobial agent are encapsulated and those wherein a plurality or cluster of such particles are encapsulated within a single microcapsule. Support for these amendments is found at page 13, line 26 through page 14, line 13.
- New claims 59-62 set forth additional dependent claims concerning the aforementioned two lines of claims as well as the ranges of acceptable particle sizes associated with each. Again, support for these new claims is found at page 13, line 26 through page 14, line 13.

No new matter has been entered by any of the foregoing amendments or new claims. It is respectfully requested that the amendments and new claims be entered.

Claim Rejections

Rejection under 35 USC §112

Claims 51 and 53 have been rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirements. Specifically, it is alleged that the inclusion of the lower limit of 10 microns for the particle size is not supported by the specification.

By the foregoing amendments, Applicants have corrected the error and inserted particle size ranges that are fully supported by the specification as filed. Consequently, Applicants respectfully request that this rejection be withdrawn and the application passed on to allowance.

Rejection under 35 USC §103(a)

Claims 1-11, 13-23, 38-40, 42, 44, 45 and 51-58 stand rejected under 35 USC §103(a) as being unpatentable over Hagiwara et. al. (US 4,775,585) in view of Konagaya et. al. (US 6,013,275), Takebayashi et. al. (US 6,156245), Niira et al. (US 5,556,699), Wada et. al. (US 3,981,970) and Turner et. al. (US 2004/0043341). The cited art is said to teach the following: 1) Hagiwara et al. teach the incorporation of antibacterial zeolite particles in polymers such as ABS; 2) Konagaya et al. teach that the antibacterial activity of silver zeolite can be increased by incorporating the same in a hydrophilic substance of therein defined chemistry and that the same can be further incorporated into a suitable thermoplastic or thermosetting resin; 3) Takebayashi et. al. teach a method of encapsulating silver zeolite with acrylic acid copolymers of average diameter of 0.03 to 300 micrometers; 4) Niira et al. teach antibiotic silver zeolites further incorporating ammonium ions for the prevention of discoloration of resins into which they are incorporated; 5) Wada et al. teach ion-exchange mechanisms involving zeolites, especially silver zeolites, including an exchange process whereby nitric acid is introduced to silver zeolite with the result being hydrogen zeolite, silver nitrate and excess nitric acid; and 6) Turner et. al. teaches that sodium nitrate reduces discoloration caused by silver.

Reiterating its prior rejection, the Patent Office acknowledges that the cited art does not expressly disclose a silver zeolite encapsulated with an acrylic resin, especially poly (hydroxyethyl methacrylate), having an average diameter of about 2000 microns or less,

optionally further comprising an ammonium salt or sodium nitrate or optionally further incorporated into an addition polymer, especially ABS. However, the Patent Office asserts that the art amply suggests incorporating the same silver zeolites into polymers such as ABS; the combination of antibacterial silver zeolites and hydrophilic polymers, such as acrylics, including hydroxyethyl methacrylic polymers; the use of ammonium ions and the exchange of silver with sodium ions and nitric acid. As such, the Patent Office alleges that it would have been well within the skill of the art and one skilled in the art would have been motivated to modify the prior art as above the expectation that the combination of antibacterial silver zeolites and hydrophilic polymers, such as hydroxyethyl methacrylic polymers would result in increased antibacterial activity, that the addition of ammonium ions would inhibit discoloration of polymer resins, such as ABS, in which the antibacterial zeolite/hydrophilic polymer is incorporated and that the addition of a salt of sodium ion and nitric acid, i.e. sodium nitrate, would drive the silver ions out of the zeolite thereby increasing the amount of free silver ions available for antibacterial effect.

The Patent Office states that it has duly considered Applicants' prior arguments but do not deem them persuasive, particularly in light of Applicants' alleged argument against the references individually rather than the combination. The Patent Office asserts that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference, nor that the claimed invention must be expressly suggested in any one or all of the references, but what the combined teaching of the references would have suggested to one of ordinary skill in the art.

Applicants respectfully traverse the Patent Office's positions as a whole as well as individually. The Patent Office has failed to appreciate Applicants' invention, has failed to consider the whole of the teachings and limitations of the cited references and has misapplied the relied upon case law in this instance.

The Patent Office is in part correct and in part incorrect in its interpretation and application of the law. To establish a *prima facie* case of obviousness, there must be 1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings, 2) a reasonable expectation of success in the prior art, and 3) the prior art reference(s)

must teach or suggest all the claim limitations. That all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the references. The mere fact that they can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. Furthermore, it is well established that if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. (MPEP 2143)

As set forth in the prior response, Applicants' acknowledge that attacking the individual references is not, in and of itself, sufficient to overcome a rejection; however, each reference must be assessed on its own merit to ascertain its teachings, it applicability to the technology of the claimed invention as well as of the secondary or primary reference with which it is being combined, if any, etc. And, while the Patent Office is correct that the claimed invention need not be expressly suggested, there is still an absolute requirement that there be some motivation, suggestion or incentive supporting the modification of the primary reference by the secondary reference to arrive at the claimed invention. (See e.g., In re Geiger, 2 PQ2d 1276 (CAFC 1985)). The mere fact that the references can be combined does not render the resultant combination obvious: more is needed including a motivation or suggestion for the combination, an expectation that the combination would provide the claimed result and do so without contradicting or compromising the properties, objectives or teachings of the references being combined. Furthermore, the Patent Office cannot pick out passages or elements of a prior art reference in support of its position while ignoring the rest of the teachings and objectives of that reference.

Turning to the claims of the instant application, it can be seen that there are four distinct aspects of the claimed invention. Independent Claim 1 is a linking claim and relates to microcapsules comprising the antimicrobial agent and a hydrophilic polymer where the microcapsule comprises either a discrete particle of an antimicrobial agent coated or encapsulated with the hydrophilic polymer (Claim 22) or a discrete micro-sized particle of a hydrophilic polymer having dispersed or encased therein a plurality or cluster of discrete particles of the antimicrobial agent (Claim 23). Similarly, Independent Claim 38 is a linking

claim and relates to polymer compositions comprising the microcapsules of claim 1 in a matrix polymer, the selection of the matrix polymer and hydrophilic polymer being such that the microcapsules are present as a discrete phase. Dependent claims 57 and 58 define the microcapsule as being either a discrete particle of an antimicrobial agent coated or encapsulated with the hydrophilic polymer or a discrete particle of a hydrophilic polymer having dispersed or encased therein a plurality or cluster of discrete particles of the antimicrobial agent, respectively.

Each aspect has different advantages and performance capabilities and methods of production. For example, in those instances where a discrete particle of the antimicrobial agent is coated, the focus is to increase the particle size so as to increase the likelihood that one or more particles will touch or be near enough the surface of the composition into which it is incorporated so as to allow for the release of the active antimicrobial agent from the antimicrobial agent. The particle size limitation of this form of the encapsulated antimicrobial agent is determined, in part, by the particle size of the antimicrobial agent itself and the encapsulation processes that can be used to coating the individual particles. Too thin a coating and there is insufficient increase in the particle size to achieve the objective of increasing the likelihood of surface contact or sufficiently close proximity to the surface to be efficacious. Too thick a coating and the path that the active must travel is too long resulting in a very slow release.

In the instance of the microcapsule comprising a plurality or cluster of particles of the antimicrobial agent in the hydrophilic polymer, size is markedly increased due to the presence of a plurality of the antimicrobial agent particles. And, since the particles are dispersed in the hydrophilic polymer, the path from at least one or more particles or the antimicrobial agent to the surface of the microcapsule is small so that release or efficacy is not delayed and, more importantly, because a number of particles of the antimicrobial agent are present in the microcapsule, all of the antimicrobial active agent is available to provide antimicrobial protection. Thus, these microcapsules serve as high concentration reservoirs of the antimicrobial active. Additionally, there are more options for the manufacture of these microcapsules than for the encapsulation of individual particles of the antimicrobial agent: ones that are comparatively less expensive and more suited for large scale manufacture.

When used as antimicrobial additives for polymer compositions, each of these microcapsules has distinct advantages over the state of the art as well as each other. Generally speaking, encapsulation allows one to enhance antimicrobial efficacy without adversely affecting properties of the matrix polymer into which it is incorporated. They also allow one to control or regulate the efficacy of a given polymer, especially where the matrix polymer into which they are to be incorporated is also hydrophilic. Further, encapsulation of the antimicrobial agent in accordance with the present invention has been found to limit or essentially limit any discoloration related to the use of the antimicrobial agent to the encapsulating polymer: thus, reducing if not eliminating the appearance of discoloration of the films or articles into which they are incorporated. In essence, this means that the particular antimicrobial agents can now be used in polymer compositions in which the unencapsulated materials are unsuitable due to concerns with discoloration.

In addition to the foregoing general benefits, which are by no means the only general benefits, each type of microcapsule has their own attributes and benefits that are unique to each. For example, while the individually encapsulated antimicrobial agents will likely require a higher loading, on a weight for weight basis, than the microcapsules having a plurality of particles of the antimicrobial agent, to provide the same level of efficacy, their smaller size makes them more appropriate for coating and thin film applications or in applications where surface roughness is a particular issue, e.g., fibers and medical catheters. Of course, they still can be used effectively and advantageously (as compared to the uncoated antimicrobial agent) in thicker coatings, films, sheets, molding and other applications as well.

On the other hand, the larger hydrophilic polymer particles having the antimicrobial agent dispersed therein are especially suited for thicker coatings, films, sheets, molding and other applications. Of particular benefit here is the large reservoir of antimicrobial active present in each microcapsule. This reservoir provides for improved longevity of antimicrobial activity as compared to the foregoing discrete encapsulated particles and markedly improved longevity as compared to the unencapsulated antimicrobial agent. Furthermore, and in following, such antimicrobial agents are now rendered suitable for use in polymers and coating compositions to be used in applications in very humid environments or where the surface of the article is subject to water flow. While these microcapsules have a much larger particle size than

the individually encapsulated antimicrobial agent particles, the particle size is still able to be held quite small, less than 3000 microns, preferably less than about 2000 microns, so that there is little if any impact on the performance and/or characteristics of the polymer matrix into which they are incorporated. Of course, it is possible and may be desirable to select a particular hydrophilic polymer and particle size of the microcapsule that does affect or modify the physical properties/characteristics of the matrix polymer into which the microcapsules are to be incorporated. For example, the hydrophilic polymer may be such that it acts as an impact modifier to the matrix polymer. Finally, as with the individually encapsulated particles, the discoloration associated with the antimicrobial agents, or at least with the compounding of the antimicrobial agent in a polymer is now limited to the hydrophilic microcapsules and will not translate to the matrix polymer into which they are themselves incorporated.

Having clearly and concisely set forth the various aspects and a number of the attributes of the present invention, we now turn to the references cited and arguments made by the Patent Office against patentability. Unfortunately, one difficulty in assessing the rejection is the Patent Office's failure to clearly ascribe its rejections to the various claims and/or the distinct aspects of the present invention as elucidated above. It is not clear which rejections pertain to the microcapsules and which to the polymer compositions into which they have been incorporated. Furthermore, while the Patent Office identifies the element(s) from each of the references upon which it relies in making its rejections, it does not set forth the motivation or in any way point to the teaching or suggestion in the references or in the general skill of the art to warrant the combination or the expectation of the results as attained by Applicants. Applicants have raised these issued previously, yet no clarification has been provided in the following Office Actions. Should the Patent Office determine that any or all claims, as amended, still warrant a rejection, it is respectfully requested that the Patent Office clearly identify which claims are being rejected under which references, what elements of the references are being relied upon and where each presents the motivation or suggestion for the combination as well as the expectation of the desired result and, finally, where each of the claim limitations of the present claims are recited.

Hagiwara in view of Konagaya

Applicants do not dispute the alleged teachings of Hagiwara et. al., i.e., the incorporation of silver zeolites in various polymers, including ABS. Applicants also appreciate the Patent

Office's remarks relating to Konagaya et. al.; however, Applicants believe the Patent Office has given more meaning and interpretation to the teaching of Konagaya et. al. than is present or warranted. Konagaya et. al. teach that organic and/or inorganic antimicrobial agents when incorporated into hydrophilic polymers have a marked increase in antimicrobial efficacy as compared to their use in non-hydrophilic polymers. Konagaya et. al. also teach that these compositions may be further mixed with another "suitable" thermoplastic or thermosetting resins. Though Konagaya et. al. is silent as to what qualifies a polymer as being "suitable", in looking at Konagaya et. al. as a whole, it is clear that the hydrophilic polymer and the other polymer must be wholly or significantly miscible. Konagaya et. al. is also silent as to the relative amounts by which the hydrophilic and other "suitable" polymer are to be employed; however, it is clear that the amount must be such as to impart a hydrophilic characteristic to the mixture. No other conclusion is possible since the whole premise of Konagaya et. al. is that organic and/or inorganic antimicrobial agents perform better when incorporated into hydrophilic materials. Furthermore, this conclusion is fully supported by and consistent with the overall teaching and specification of Konagaya et. al. For example, if one looks at the list of hydrophilic and non-hydrophilic monomers that may be used in making the antimicrobial compositions, they replicate, to a large extent, the monomers from which the other "suitable" polymers are made or they are ones that those skilled in the art of polymer compounding and blends would readily recognize as being miscible with each other. Thus, by properly selecting "suitable" polymers of like or compatible monomers or polymer combinations, one can ensure that miscibility or at least partial miscibility can be achieved.

It is well established in polymer chemistry that miscible blends will take on properties and characteristics of both polymers; though the extent to which such properties are manifested depends upon the relative amounts of each. Thus, miscible and partially miscible blends of a hydrophilic polymer with a non-hydrophilic polymer will result in a composition having at least some hydrophilic characteristics. This is clearly the very objective sought by Konagaya et. al. in order to achieve and realize the enhanced antimicrobial efficacy of which it speaks. Indeed, this conclusion is consistent with and fully supported by the examples of Konagaya et. al. As pointed out in the prior response and its accompanying declaration, in formulating compositions within the scope of its teaching, Konagaya et. al. either selected monomers and/or polymers which

would allow for a transesterification during the mixing process so as to create a new hydrophilic copolymer or if transesterification was not contemplated, the polymers selected tended to be of lower molecular weight and ones that were and would be recognized by those skilled in the art as wholly or partly miscible.

Certainly, as set forth by the Patent Office, the teachings of Hagiwara et. al. and Konagaya et. al. may be combined; however, the combined teaching is only that one could look to Hagiwara et. al. for additional hydrophilic polymers and/or monomers and other "suitable" polymers that could be used in creating new hydrophilic compositions, which when combined with an antimicrobial agent, will manifest an enhancement in antimicrobial efficacy as opposed to the use of the same antimicrobial agents in a non-hydrophilic composition, i.e., that the selection of the other polymers must be one that would achieve a miscible or partially miscible blend so as to impart hydrophilicity to such blend. In this respect, it is interesting to note that while many of the specific polymers and classes of polymers mentioned in Hagiwara et. al. are the same as those mentioned in Konagaya et. al., the latter is much more limiting, failing to include, for example, ABS resins, and limiting some of the broader classes of Hagiwara et. al. to only certain polymers and subclasses of polymers, e.g., nylon 6, nylon 6,6, nylon 11, nylon 12 and the like. Since essentially all polymers can be blended, the use of the word "suitable" combined with the limited listing of "suitable" polymers, has significance, which significance, in light of the whole of Konagaya et. al., can only mean miscibility, wholly or partially, for imparting hydrophilic characteristics to that "suitable" polymer.

Both Konagaya et. al. and the instant invention have a common, though not identical, objective, i.e., the enhancement of the antimicrobial efficacy of a given antimicrobial agent. The former achieves its objective through chemical means, i.e., by using/selecting hydrophilic materials or modifying hydrophilic properties of the composition into which they are to be incorporated. The present invention, on the other hand, while taking advantage of certain characteristics identified by Konagaya et. al., i.e., improved antimicrobial efficacy in hydrophilic polymers, achieves its objective through geometric means by increasing the effective size of the antimicrobial agent so as to increase the likelihood of surface contact/proximity and, in the case of the cluster type particles, employing highly concentrated reservoirs of the antimicrobial active. Applicants do not, or not to any significant extent, intend to modify the physical

properties of the matrix resin into which their microcapsules are to be incorporated. Konagaya et. al.'s teaching is limited to those formulations and systems or compositions that are or can be rendered hydrophilic. Applicants' invention is broader, applicable to systems that are hydrophilic and, especially, those that are non-hydrophilic. Furthermore, Applicants' compositions specifically require phase separation whereas Konagaya et. al. clearly need miscibility or homogeneous compositions. Thus, Hagiwara et. al. in view of Konagaya et. al. do not make obvious either the microcapsules or the antimicrobial compositions comprising the microcapsules of the present invention and the rejections should be withdrawn.

Hagiwara et. al. is also cited as teaching the claimed particle size; however, as noted in Applicants' prior responses, such particle size is with respect to the particle size of the antimicrobial agent itself and are consistent with the particle size of Applicants' antimicrobial agent prior to encapsulation. However, Hagiwara et. al. do not teach, suggest or motivate one to increase the effective particle size of a solid inorganic antimicrobial agent by encapsulating the same, and certainly not do so in the range of sizes as claimed by Applicants.

In light of the foregoing and the further arguments and statements of the prior response and declaration of Jeffrey A Trogolo and in view of the clear claim language of the polymer composition claims which require a two-phase system wherein the dispersed phase has a given particle size and matrix polymer of given hydrophilicity, any presumption of *prima facie* obviousness has been rebutted and the rejection should be withdrawn and the application passed on to allowance.

Hagiwara in view of Konagaya and Takebayashi et. al.

Takebayashi et. al. is cited for showing the microencapsulation of various solid materials, including silver zeolites, with various polymers, including acrylic acid copolymers, wherein the average diameter of the obtained microcapsule is usually from 0.03 to 300 micometers. Applicants acknowledge Takebayashi et. al. and its teaching of an encapsulation method for silver zeolites; however, Applicants neither claim nor profess that they are the first to encapsulate silver zeolites. Indeed, Takebayashi et. al., Turner et. al. (cited by the Patent Office) and Hishida et. al. (JP 04-066512 previously cited by Applicants and resubmitted concurrently with this response in full translation) all disclose the microencapsulation (coating) of individual silver zeolite particles with hydrophobic polymers. Further, as suggested by the Patent Office

and as stated in Takebayashi et. al. the resultant particle size is largely determined by the initial particle size of the antimicrobial agent being coated. (see Col. 6, lines 28-31).

None of these three references, however, teach or suggest the encapsulation or coating of such solid antimicrobial agents with a hydrophilic polymer. Indeed, all employ a hydrophobic coating and, in the case of Takebayashi et. al., one that is apparently water soluble. Where Takebayashi et. al. acknowledge that the coating materials use or to be used are not traditionally water soluble, they teach one how to make the same water soluble (See col. 5, lines 4-13). Such would be consistent with the purpose for which the materials of Takebayashi et. al. are prepared, i.e., as a protective layer for the core fungicide, pesticide, or pharmacological agents. The coating protects the underlying core material for improved efficacy, decreased toxicity and stabilization. As is well known in the pesticide, fungicide and pharmacological arts, such encapsulation protects the core material until the material is exposed to rain or dispersed in water for application (in the case of pesticides and fungicides) or is consumed (in the case of pesticides and pharmacological agents). Indeed, such encapsulation allows for the time-release characteristics often touted with such pesticide and pharmacological agents.

While Takebayashi et. al. do employ acrylic acid copolymers in the preparation of their encapsulated silver zeolites, it is employed as a middle or tie layer which holds a hydrophobic polymer outer layer or coating to the core particle, the silver zeolite. Furthermore, those skilled in the art would readily recognize that the nature of the specific middle layer materials (as well as many of the hydrophobic coating materials themselves) disclosed are such that they would decompose or otherwise degrade if the so encapsulated particles were to be compounded into another polymer by, for example, melt blending: the primary method by which the antimicrobial polymer compositions of the present invention are made. In essence these soft, gelatinous materials have very low or poor thermal resistance and would be unable to endure the high processing temperatures of melt blending.

Thus, Takebayashi et. al., taken individually or together with Turner et. al. and Hishida et. al., actually teach away from the present invention rather than towards it. Hishida et. al. teach that the silver zeolites, especially the surface thereof, are inherently hydrophilic and that such hydrophilicity creates significant problems for their use and performance. In order to overcome those problems, Hishida et. al. modify the silver zeolite, and thus the surface thereof, to

effectively render the same hydrophobic by coating the particles with a hydrophobic polymer. Problems with the hydrophilic nature of the silver zeolites is also acknowledged by Turner et. al. who also elect to coat the silver zeolite with a hydrophobic polymer in order to make them perform better. Both of these references would seem to be more pertinent than Takebayashi et. al. since each modifies the silver zeolite to enhance its performance in a polymer composition whereas Takebayashi et. al. merely encapsulates the silver zeolite for environmental, health and safety reasons. The latter's encapsulated silver zeolites are intended to be applied as is (as a dust) or in a liquid, preferably water, carrier. No mention or suggestion is made for the incorporation of their encapsulated silver zeolites into polymer compositions nor would such suggestion be present since their selection of coating materials is such that they would not be appropriate for such a use, particularly where the encapsulated particle is to be melt blended into another polymer. Thus, while Takebayashi et. al. may, at best, be a proper reference relative to the claims of the instant application directed to the microcapsules themselves, it does not appear relevant nor applicable to the claims for the antimicrobial compositions containing said microcapsules and should be withdrawn with respect to those claims.

Takebayashi et. al. is also cited as teaching the relevant particle size; however, Takebayashi et. al. merely mention that particle size of their encapsulated agents is a function of the underlying or core solid particle being encapsulated. While this is somewhat true for and pertinent to those of Applicants' claims directed to the individually encapsulated or coated antimicrobial agent, since the starting particle size sets the initial starting point from which diameter of Applicants' microcapsules are enlarged, it does not address Applicants' intentional increase of particle size to a point that significantly increases the probability that the particle will participate antimicrobially once incorporated into a polymer. Specifically, Takebayashi et. al. is concerned only with providing the protective coating to its solid particles whereas Applicants must achieve a coating thickness of a material degree, one that will significantly increase the probability that any one particle will touch or be of sufficiently close proximity to the surface of the polymer matrix in which it is incorporated to be effective in providing antimicrobial activity. Nowhere does Takebayashi et. al. teach, suggest or motivate one to use hydrophilic coatings or to intentionally increase the particle size in order to achieve such a result. Thus, in regard to particle size of the individually coated antimicrobial agent, Takebayashi et. al. do nothing to

suggest that certain particle sizes be attained for achieving the desired result of enhanced antimicrobial activity when incorporated into a polymer matrix: the purpose for which Applicants' microcapsules are being made.

As acknowledged, Takebayashi et. al. may be pertinent to the encapsulation of individual particles of an inorganic agent, including, as shown, silver zeolite; however, nothing in Takebayashi et. al. or the other two patent publications mentioned above, alone or in combination, suggest, teach or motivate one to form particles of a polymer, let alone a hydrophilic polymer, having encased therein a plurality of particles of an antimicrobial agent. As discussed earlier, these latter microcapsules or particles are distinct from and have attributes and applications not found with the encapsulation of individual particles as taught by each of these documents. Thus, even if there were a basis for the arguments against patentability of the latter, such would not be pertinent or applicable to question of patentability of the former.

Applicants acknowledge the Patent Office's remarks concerning Applicants' apparent failure to provide evidence of criticality and their use of the term "about" in reference to the claimed particle sizes of their microcapsules and respectfully traverse the same. In order to establish *prima facie* obviousness it is the burden of the Patent Office to show, among other critical aspects, that the art teaches the claim limitations. The Patent Office has not shown such limitations either with respect to the encapsulation with the claimed hydrophilic materials or the claimed particle sizes. Furthermore, the Patent Office has provided no basis to question the claim limitations or criticality thereof or, more importantly, the statements in support thereof set forth in the Declaration of Dr. Trogolo in the prior response. Thus, the Patent Office's arguments relative to particle size are unsupported and, in any event, fully rebutted in light of the discussion presented in this and Applicant's prior communications.

In light of the foregoing, Applicants believe they have fully addressed and rebutted any claim of obviousness with respect to the claimed microcapsules themselves. As such, since the microcapsules are themselves patentable, compositions that incorporate the same for the purpose and benefits set forth in the specification must, by definition, also be patentable. Therefore, the rejection of the instant claims over Hagiwara et. al. in view of Konagaya et. al. and Takebayashi et. al. should also be withdrawn and the claims passed on to allowance.

Even if the Patent Office should remain steadfast in its rejections of one or both types of microcapsules, as distinguished above, these references do not make obvious polymer compositions having said microcapsules incorporated therein. First, Applicants contend that Takebayashi et. al. is not properly combinable with either Hagiwara et. al. or Konagaya et. al. since one would not look to incorporate an encapsulated antimicrobial agent into a polymer composition wherein the encapsulating material is a water soluble material and the therein encapsulated antimicrobial agent is only capable of acting once the water soluble material is dissolved. Since the matrix polymer into which it would theoretically be incorporated would not allow for the dissolution of the water soluble coating, the antimicrobial agent would essentially be ineffective. Regardless, since Turner et. al. and Hishida et. al. also disclose encapsulated antimicrobial agents, in an effort to expedite the allowance and issuance of a patent on the instant invention, Applicants will nevertheless discuss the rejection, as well as the following rejections, as if these two citations rather than Takebayashi et. al. were the secondary reference.

While Applicants have acknowledged the prior art teaching of the encapsulation of individual particles of antimicrobial agents, none of the previously mentioned references, alone or in combination, teach, suggest or motivate one to prepare such individual particles wherein the coating is a hydrophilic polymer. In fact, as discussed, each teaches away from the encapsulation with a hydrophilic material. Furthermore, none of these references, alone or in combination with Hagiwara et. al. and/or Konagaya et. al., teach, suggest or motivate one to incorporate such hydrophilic polymer coated or encapsulated particles into a polymer composition for enhanced performance. Similarly, none of the aforementioned encapsulation references, alone or in combination, suggest, teach or motivate one to form particles of a polymer, let alone a hydrophilic polymer, having encased therein a plurality of particles of an antimicrobial agent. More importantly, none of these references alone or in combination with Hagiwara et. al. and/or Konagaya et. al. suggest the use of such antimicrobial agent modified polymer particles, and certainly not where said polymer is a hydrophilic polymer, in a polymer composition for enhancing and/or modifying, among other aspects, the antimicrobial efficacy and longevity of so formed compositions.

In light of the art's failure to suggest or motivate one to make the microcapsules and/or the microcapsule containing compositions of the present invention, to expect the markedly

enhanced performance and other benefits of the present invention, or the specific claim limitations of the instant claims, the allegation of prima facie obviousness is rebutted and, it is believed, the claims, as amended, are clearly unobvious and, thus, patentable, over the art.

Hagiwara et. al. in view of Konagaya et. al. and Takebayashi et. al. further in view of Niira et. al.

Niira et. al. is cited as teaching the incorporation of ammonium ions for effectively preventing discoloration of the resins into which antimicrobial zeolites are incorporated. Applicants have previously acknowledged the prior art teaching of the use of ammonium ions in combination with a silver ion-exchange antimicrobial agent for the prevention of discoloration; however, such an admission as well as the teaching of Niira et. al., in general, does not add to the alleged strength of the Patent Office's rejection of the independent claims. Niira et. al. teach much the same as Hagiwara et. al. with the exception that its polymer compositions are formed into films. There is nothing to suggest, infer or motivate one to create encapsulated antimicrobial agents, either as individually coated antimicrobial agent particles or as micro-sized particles of a hydrophilic polymer having dispersed therein an antimicrobial agent, and to employ those encapsulated materials as a distinct phase in a polymer composition. Applicants did not intend for their comment in the prior response to infer that no two-phase systems could be formed into films; however, they and those skilled in the polymer art would readily recognize that a two-phase system is not **generally** suitable for forming polymer films. Regardless, none of the references, Niira et. al. included, teach or suggest the preparation and use of microcapsules of a hydrophilic polymer having incorporated therein antimicrobial agents as additives for polymer compositions. None of the references alone or combined require or disclose the specific claim limitations of hydrophilicity, particle size, and, in the case of the polymer compositions, phase separation.

Furthermore, relative to the teachings of Niira et. al., an additional unique and unexpected benefit of Applicants' compositions is that the ammonium ions will tend to react with those color-forming constituents in the hydrophilic polymer encapsulating the antimicrobial agent rather than the matrix polymer, thereby further reducing the likelihood of discoloration of the latter. Thus, those reactions which oftentimes cause discoloration or which help prevent discoloration, as with the use of the ammonium ions, are now essentially restricted to the

hydrophilic material and do not, at least not to any significant extent, extend into the polymer matrix (See page 7, line 29 through page 8, line 2). The Patent Office has responded that it is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant referencing In re Linter and In re Dillon (see quotes in Office Action). This statement, however, requires that the art be such that there exists motivation for making the combination for the reason set forth in the art, which reason need not be the same as the patent applicant's. Thus, while this line of argument may be appropriate when speaking of the microcapsules themselves, it is not applicable to the polymer compositions containing the microcapsules.

Hagiwara et. al. in view of Konagaya et. al., Takebayashi et. al., and Niira et. al. further in view of Wada et. al. and Turner et. al.

In an effort to counter Applicants' prior argument against the teaching and relevance of Wada et. al. to those aspects of the present invention wherein a dopant, particularly sodium nitrate, is added to the hydrophilic polymer, the Patent Office has now cited Turner et. al. Presumably, Turner et. al. is employed to show the addition of sodium nitrate to an antimicrobial composition having silver as the antimicrobial agent in light of Wada et. el.'s failure to recite or mention sodium nitrate. However, this combination of references is inappropriate and, even if appropriate, inoperable and inapplicable to the present invention.

First, the two references are not combinable. Wada et. al. is concerned with the recovery of metals from a solution whereas Turner et. al. is concerned with the production of antimicrobial contact lenses. One looking to make antimicrobial contact lenses would not look to metal recovery art for ideas on how to improve their products/technology. Furthermore, Wada et. al. teach an exchange reaction wherein a specific zeolitic material composed of alumino/ferro-phosphate/arsenate, identified as zeolite OTW, is used to capture free silver ions and then washed with concentrated nitric acid to remove and recover the silver as silver nitrate. Turner et. al. teach antimicrobial contact lenses wherein the contact lens composition may contain an oxidizing agent for oxidizing silver (Ag^0) to (Ag^{+1}) and (Ag^{+2}) (See Paragraph 62). These are two entirely different technologies, using entirely different materials and chemistries for entirely different purposes.

Secondly, Wada et. al. is non-analogous art to the present invention. Wada et. al. is concerned with the recovery of metals from a solution whereas the present invention is concerned with new antimicrobial additives for polymer coatings and compositions and the there formed coatings and compositions. One would not look to the metal recovery art for ideas and technology on how to improve such antimicrobial additives or the compositions incorporating the same.

Even if, through some far fetched stretch of the imagination, one were to conclude that the two references were combinable and that they were analogous to the present invention, their respective teachings are at odds and provide no guidance as to the present invention. Turner et. al. teach sodium nitrate as an oxidizing agent for metallic silver; however, both Applicants and Wada et. al. already employ ionic silver; thus, there would be no purpose, from Turner et. al.'s perspective, for using sodium nitrate or any oxidizing agent. Furthermore, based on Wada et. al.'s stated relative selectivity of the zeolite OTW for various cations (including specifically silver, sodium and hydrogen), one would not expect sodium to be effective for inducing release of the silver ion from the zeolite. As presented, the selectivity of the zeolite OTW for sodium is far, far, far lower than for silver and far, far lower than for the hydrogen proton offered by nitric acid. Indeed, the zeolite-OTW had negligible pick up of sodium ions as compared to silver ions even though the solution in which it was placed has nearly 50 times as much free sodium ions as silver ions (See table at Col. 2, lines 49-58). Conversely, one would not use nitric acid in the teaching of Turner et. al. or in applicants' invention as it would likely degrade the polymer matrix and/or render the compositions unsuitable for their intended purpose. Additionally, in the case of Turner et. al. the presence of nitric acid would be unsuitable even if one could stabilize it: one certainly wouldn't want to put nitric acid in one's eye.

For these reasons and those set forth in the prior response, it is clear that neither Wada et. nor Turner et. al. nor the combination thereof with the prior references in any way make obvious the use of a dopant to enhance and accelerate the release of an antimicrobial metal ion in the microcapsules or polymer compositions as claimed by the present invention. Thus, the rejection of the claims directed towards the use of the dopant should be withdrawn and the claims passed on to allowance.

Conclusion

Contrary to the assertions of the Patent Office, none of the cited art, alone or in combination, speaks of, suggests, infers or motivates one to produce the particulate, encapsulated antimicrobial agents of the present invention and employ them in polymer compositions as a discrete second phase for enhanced antimicrobial efficacy and control. Similarly, none of the cited art, alone or in combination, would suggest the marked benefits attained by compositions made in accordance with the teaching of the present invention as described in the specification and as shown by way of additional examples in Applicants corresponding Published International PCT Patent Application No. WO03/055941 .

Though the Patent Office has searched through a number of patent publication to find elements that appeared to disclose elements according the instant invention, it has no provided any basis or pointed to any text or passages of the references which would explain why those elements are to be combined or even that they could be combined. Nothing in the art supports or suggests i) the encapsulation of individual particles of an inorganic antimicrobial agent with a hydrophilic polymer, ii) the preparation of micro-sized particles comprising a hydrophilic polymer having dispersed therein an inorganic antimicrobial agent, iii) the use of (i) or (ii) as an antimicrobial additive in a polymer composition, iv) that the compositions of iii have markedly and unexpectedly better performance than similar polymer compositions wherein the antimicrobial agent is not encapsulated with a hydrophilic polymer, etc. Instead, at best, the Patent Office has shown i) that the efficacy of antimicrobial agents is better when incorporated into a hydrophilic polymer, ii) that one can produce hydrophilic polymers or blends a hydrophilic polymer with a "suitable" polymer to make the latter hydrophilic so as to realize the benefit of its teaching, iii) that one can enhance the performance and utility of silver zeolites (including overcoming the problems associated with the inherent hydrophilic nature of the unencapsulated silver zeolite) by encapsulating the same in hydrophobic materials, etc. Clearly, the Patent Office has failed to present a valid argument of prima facie obviousness and, in any event, Applicants have fully rebutted any such claim. Consequently, Applicants believe the claims as currently presented represent patentable subject matter and respectfully request that the rejections be withdrawn and the application passed on to allowance.

Petition For Extension of Time

By this response, Applicants hereby petition for a one-month extension of time; thereby extending the response period from January 5, 2004 to and including February 7, 2005, February 5, 2005 falling on a Saturday. Enclosed is payment of the Petition Fee in the amount of $60.00.

Claims Fees

No addition fees are necessary as the total number of claims remaining after this amendment (43) does not exceed the highest number of claims previously paid for (50), or have any new independent claims been added.

Applicants believe all matters raised in the Office Action have been fully addressed. Should there be any questions, please contact the undersigned, Applicant's attorney.

Respectfully submitted,

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